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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,773	11/04/2003	Hongming Chen	TPIP020	5482

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EXAMINER	
HYUN, PAUL SANG HWA	

ART UNIT	PAPER NUMBER
1743	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/700,773	CHEN ET AL.	
	Examiner	Art Unit	
	Paul S. Hyun	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-22* is/are pending in the application.

4a) Of the above claim(s) *1-5 and 7-18* is/are withdrawn from consideration.

5)☐ Claim(s) ____ is/are allowed.

6)☒ Claim(s) *19-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/7/04, 10/16/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. ____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

REMARKS

In response to the restriction requirement dated 12/29/06, Applicants cancelled claim 6, withdrew claims 1-5 and 7-18, and added new claims 19-22, and elected the prosecution of the new claims, alleging that the new claims read on the elected species. In summary, only claims 19-22 will be examined on the merits. Claims 1-5 and 7-18 are withdrawn from further consideration by the Examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims **19-22** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 recites that the concentration of the "sample" is greater than about 1 mg/mL. However, the claim does not recite that the sample, which comprises a compound-of-interest and a liquid excipient, is diluted or mixed with another substance. Therefore, it is unclear with respect to what the concentration is referring.

The scope of step (b) in claim 19 with respect to steps (a), (c) and (d) is also unclear. First, according to step (a), an array of the samples has already been prepared. Therefore, it is unclear what function step (b) is intended to accomplish. Second, the claim does not specify to where the excipient is dispensed. It is unclear how step (b) fits within the scope of steps (a), (c) and (d).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims **19-22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. (US 6,957,151 B2) in view of Popli et al. (US 5,616,621) and Desrosiers et al. (US 2003/0119060 A1).

Cheng et al. disclose a method for determining and ranking the solubility of a pharmaceutical drug in different concentrations and types of excipients (see Tables 1-3 and [0035]-[0038]). Cheng et al. disclose that the experiment is pertinent because many parameters, including the solubility of pharmaceutical compounds in excipients, affect the effectiveness of a drug (see [0003]). The method disclosed by Cheng et al. differs from the claimed method in that Cheng et al. do not disclose that the viscosity of the sample is greater than 100 centipoise. Cheng et al. also do not disclose that the method is conducted in an array-format or that the array comprises at least 94 samples. Lastly, Cheng et al. do not disclose that decomposed or degraded samples are excluded from the method.

With respect to the viscosity of the sample, the method disclosed by Cheng et al. is directed towards inhaled pharmaceutical drugs. Nonetheless, it would have been obvious to perform the method disclosed Cheng et al. for other drugs to determine their solubility in various excipients. Popli et al. disclose a drug composition (pharmaceutically active compound + liquid excipient) wherein the viscosity of the drug composition is greater than 100 centipoise (see claim 1). It would have been obvious to one of ordinary skill in the art to perform the method disclosed by Cheng et al. using the drug composition disclosed by Popli et al. as the test subject to determine the optimal per dosage concentration of the pharmaceutically active compound.

With respect to the array, Desrosiers et al. disclose a method for determining the solubility of pharmaceutical drugs in different solvents wherein the method is carried out in an array format on a microplate (see [0194]). In light of the disclosure of Desrosiers et

al., it would have been obvious to one of ordinary skill in the art to conduct the method disclosed by Cheng et al. on a microplate. Conducting the method on a microplate would facilitate the identification and the organization of the samples.

With respect to the 94 samples, it would have been obvious to one of ordinary skill in the art to expand the range of parameters (e.g. concentration of excipient, type of excipient) in the method disclosed by Cheng et al. such that more than 94 samples are prepared so that a more thorough data can be obtained.

With regards to claim 20, although Cheng et al. do not explicitly disclose that degraded or decomposed samples are thrown out from the experiment, it would have been obvious to one of ordinary skill in the art to selectively exclude decomposed or degraded samples from the method disclosed by Cheng et al. to prevent skewed data caused by defective samples.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul S. Hyun whose telephone number is (571)-272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PSH
7/17/07

Jill Warden
Supervisory Patent Examiner
Technology Center 1700